

Application No.: 10/627,245  
Amendment Dated: October 16, 2006  
Reply to Office Action of May 15, 2006

### REMARKS

By a Final Office Action dated May 15, 2006 in the file of the above-identified application, the Examiner rejected all the claims of the application based indefiniteness and on prior art. Based on the amendments to the claims and the comments contained herein, and on the Request for Continued Examination submitted herewith, reconsideration of the merits of this patent application is respectfully requested.

The previous claims in this application were all rejected under §112, second paragraph, for the use of the language atrial-like, ventricular-like and nodal-like referring the action potentials. As understood by the applicants, the Examiner felt that this language formulation could not be supported by the specification.

In the amended claims above, the applicants propose a different language formulation that does not require a precise description of the characteristics of the action potential. Instead the cells are classified as to type of cardiac cell based on the action potential actually captured. The applicants' specification makes it clear that this is enabled, since the applicants were able to do that using the procedures described in the specification. It is requested that this ground of rejection be reconsidered in view of these amendments.

The first prior art rejection in the Office Action was under §102 over Bosch et al. or Li et al. The Examiner helpfully noted that if the claims were amended to recite that the method includes the step of deriving cardiomyocytes from human embryonic stem cells, that this grounds of rejection would be overcome. The applicants have done that above. So it is believed that this rejection is now moot.

The next rejection in the Office Action was under §102(e) over Gepstein et al. It is believed that the claim amendments overcome this ground of rejection. Gepstein does not show or make obvious the step of using the transmembrane action potential of the cardiomyocyte to characterize the type of cardiomyocyte being used in the assay. Characterizing the type of cardiomyocytes produced from human ES cells is not a trivial problem, since there are not well identified diagnostic cell surface markers as there are for other cell types. Nothing in Gepstein suggests how one would distinguish an atrial cardiomyocyte from a ventricular cardiomyocyte. Because the ion channels and the electrical properties of atrial, nodal and ventricular cells are quite different, the response to pharmacological interventions will be quite different and have distinct implications. For

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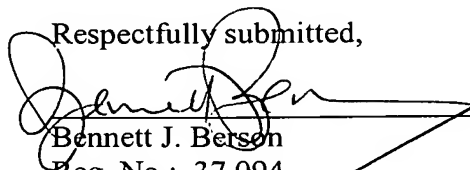
example, some agents may specifically prolong the action potential in ventricular cells which would indicate an increased risk of long QT syndrome whereas another drug may not impact the ventricular action potential but could specifically prolong the atrial action potential. The latter would indicate that an agent might be a good antiarrhythmic drug for the most common arrhythmia in the US, atrial fibrillation. Thus, a method that determines the particular cell type present allows specific interpretation of the results. The applicants' method claimed here enables the determination of cell type, and nothing in Gepstesin suggests accomplishing this. Accordingly, reconsideration of this rejection is also requested.

Finally, the Examiner imposed a rejection under §103(a) over several references including Bosch et al., Li et al., Carlsson et al., and Gepstein et al. The applicant asserts that the logic applied against the prior ground of rejection applies equally here. The concept of classifying the type of cardiomyocyte by the characteristics of the recorded transmembrane action potential is not present in any of the cited prior art. Furthermore, nothing in any of these references provides any motivation to perform such a step. Therefore, this prior art cannot make obvious the method claimed here which includes that step. Reconsideration of this last rejection is requested as well.

Accordingly, it is believed by the applicants that the rejections applied against the claims of this application should be reconsidered and withdrawn.

A separate petition for extension of time is submitted herewith so that this response will be considered as timely filed. Please charge the fee to Deposit Account No. 17-0055. A Request for Continued Examination is also filed herewith to ensure the consideration of this response.

Respectfully submitted,



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